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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,278	09/26/2000	Janet M. Hock	X-11965	5427

7590 04/30/2003

ELI LILLY AND COMPANY  
LILLY CORPORATE CENTER  
DROP CODE 1104  
INDIANAPOLIS, IN 46285

EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

14

DATE MAILED: 04/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/647,278	HOCK, JANET M.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 February 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35 and 56-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35 and 56-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4 &amp; 7</u> . | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### **I. Status of Application, Amendments, and/or Claims**

The amendment filed in Paper No. 13 on February 14, 2003 is acknowledged. Claims 17-34, and 36-55 have been canceled. Claim 35 has been amended. Claims 56-66 have been added. Claims 35 and 56-66 are pending and are under consideration. However, the requested amendment to the specification at page 47, line 8 could not be entered because "µg/kg/day" does not appear in that line.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **II. Correction of Inventorship under 37C.F.R. § 1.48**

In view of the papers filed on 2/14/2003, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(c). The inventorship of this application has been changed by the addition of Gregory A. Gaich and Willard H. Dere.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

### **III. Withdrawn Objections and/or Rejections**

The rejection of claims 17-55 under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, as set forth at page 3 of the previous Office Action (Paper No. 9, August 12, 2002), has been withdrawn in view of applicants' cancellation of claims 17-34 and 36-55, amendment to claim 35, and argument.

The rejection of claims 17-52, 54, and 55 under 35 U.S.C. §102 (b) as being anticipated by Sone et al., as set forth at pages 3-4 of the previous Office Action (Paper No. 9, August 12, 2002), has been withdrawn in view of applicants' cancellation of claims 17-34, 36-52, 54, and 55, amendment to claim 35, and argument.

The rejection of claims 17, 19, 21, 23, 25-28, 30, 32-34, 36, 38-40, 42, 43, 45-47, and 49-55 under 35 U.S.C. §102 (b) as being anticipated by Neer et al., as set forth at pages 4-5 of the previous Office Action (Paper No. 9, August 12, 2002), has been withdrawn in view of applicants' cancellation of the claims.

### **IV. Claim Rejection Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Written Description)**

(i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii) Claims 59-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 59 recites "a weekly dose of 20  $\mu\text{g}$  to 40  $\mu\text{g}$ ", which is new matter. There is no support for it in the instant specification. Claims 60-63 depend from claim 59.

#### **V. Claim Rejection Under 35 U. S. C. § 102 (b)**

The rejection of claim 35 under 35 U.S.C. §102 (b) as being anticipated by Neer et al., as set forth at pages 4-5 of the previous Office Action (Paper No. 9, August 12, 2002), remains.

New claims 56-58 and 64-66 are also rejected under 35 U.S.C. §102 (b) as being anticipated by Neer et al. (IDS No. AB, U.S. Patent No. 4,698,328, October 1987). The basis for the rejection is set forth at pages 4-5 of the previous Office Action (Paper No. 9, August 12, 2002). In view of Applicants' amendment to the claims, the rejection is set forth below for the purpose of clarity.

Claims 35, 56-58, and 64-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Neer et al. (U.S. Patent No. 4,698,328, October 1987).

Neer et al. teach a method for the treatment of osteoporosis in human subject to increase bone mass, comprising administering human PTH (1-34) in a daily dose of 100-700 units, more preferably 200-600 units, and most preferably 400-500 units (top of column 5). Based upon the calculation that 400 units = 25  $\mu\text{g}$  (used in the previous office action in Paper No. 9; source: Lindsay 1997, 1993, IDS codes CB and CD; Lane 1998, IDS code, CE), 100-700 units/day is equivalent to 6.3-43.8  $\mu\text{g}/\text{day}$  whereas 400-500 units/day is equivalent to 25-31  $\mu\text{g}/\text{day}$ . If the average conversion factor (which was obtained by averaging all the specific activity values provided by the Applicants on page

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19 of Applicants' response), 10.8 units/ $\mu$ g, is used, 100-700 units/day is equivalent to 9.2-64.8  $\mu$ g/day, 200-600 units/day is equivalent to 18.5-55.5  $\mu$ g/day, whereas 400-500 units/day is equivalent to 37-46.2  $\mu$ g/day.

Neer et al. further teach that the method of treatment is intended to be used in all diseases classified as osteoporosis, such as postmenopausal osteoporosis, senile osteoporosis, osteoporosis secondary to gonadal insufficiency, or osteoporosis that is a sequella of hyperparathyroidism or glucocorticoid excess (bottom of column 3).

Thus, the reference of Neer et al. meets the limitations of claims 35, 56-58, and 64-66.

Applicants argue that Neer et al. fail to anticipate the claimed invention because Neer et al fail to disclose the invention, either expressly or inherently, and the reference of Neer et al. is non-enabled (pages 11-16).

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons.

First, Neer et al. teach "units" are defined in terms of the International Reference Preparation of hPTHF1-3 and comparative bioassays in the chick hypercalcemic assay. Even the International Reference Preparation of hPTHF1-34 is not available, as the declarations state, an artisan would be able to obtain a conversion factor by simply searching the art, for example, by inventor's name. For example, Finkelstein et al. (JAMA, 280:1067-1073, 1998) and Finkelstein et al. (N Engl J Med, 331:1618-1623, 1994) teach that 40  $\mu$ g =500 units (12.5 units/ $\mu$ g) and the bioassay used to determine the activity of hPTH (1-34). It is noted that both papers include Neer as an author. Thus,

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one skilled in the art would be expected to obtain a conversion factor to convert the units used by Neer et al. to  $\mu\text{g}$  in view of the teachings of Neer et al.

Secondly, the conversion factor (specific activity value) for hPTH(1-34) is well known and taught in the art, even the applicants have collected 12 specific activity values, which appear to be quite consistent. By simple averaging these numbers, as the Examiner did above, the dosage of hPTH(1-34) taught by Neer et al. can be easily converted to  $\mu\text{g}/\text{day}$  from units/day.

Thirdly, since Neer et al. teach a method for the treatment of osteoporosis in human subject comprising administering human PTH (1-34) and the dosages in units can be readily converted to  $\mu\text{g}$  because the conversion factor (specific activity value) for hPTH(1-34) is well known and taught in the art or can be experimentally determined in view of the teachings of Neer et al., the reference of Neer et al. is enabled..

Furthermore, the Declaration under 37 CFR 1.132 filed on February 7, 2003 is insufficient to overcome the rejection of claim 35 and new claims 56-58, and 64-66 based upon Neer et al. as set forth in the last Office action. The Declaration under 37 CFR 1.132 filed on February 10, 2003 is also insufficient to overcome the rejection of claim 35 and new claims 56-58, and 64-66 based upon Neer et al. as set forth in the last Office action. This is because even if the "International Reference Preparation of hPTHF1-34" specified by Neer et al. were not available or the "International Reference Preparation of hPTHF1-34" were not existing (because Neer et al. made an error in referring the standard), one skilled in the art would be able to obtain a conversion factor by simply searching the art and finding the bioassay used to determine the activity of

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hPTH (1-34), or by simple analysis of the conversion factors (specific activity values) for hPTH(1-34) taught in the art. While the specific activities of hPTH (1-34) from different sources and measured using different methods vary, they are quite close to each other and quite consistent, as shown, e.g., in the specific activity values collected by the Applicants.

Therefore, the reference of Neer et al. meets the limitations of claims 35, 56-58, and 64-66 and anticipates the claimed invention.

#### **VI. Claim Objection for Minor Informalities**

Claims 35 and 59-62 are objected to because of following minor informalities: (i) Claims 35 and 59 recite "other that", which appears to be "other than"; claims 60-62 recite "A method...", which appears to be "The method...".

Appropriate correction is required.

#### **VII. Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not



mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122.

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This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

Ruixiang Li  
Examiner  
April 17, 2003

ELIZABETH KEMMERER  
PRIMARY EXAMINER